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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 631,638	08 02 2000	Kevin M. Moore	1533.0980001 SRL PAJ	8662

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03 18 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/431638

Applicant(s)

Inventor et al

Examiner

1/2/02

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/10/02
- ☒ This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-31 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-31 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5 & 6, 1/10/02 + 2/5/01
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

In a response of 1/10/02 to a restriction requirement of 12/10/01, applicants elected claims 1-31 without traverse, and canceled nonelected claims 32-45.

5 Claims examined on the merits are 1-31 which are all claims in the application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the process of claim 17 when requiring the conditions of claims 21, 23, 24, 26 and 29, and drying in (a) is to a moisture content of about 0.1% to about 20% as described by the specification (page 7, line 30), does not reasonably
20 provide enablement for other processes differing substantially from the preferred embodiments described in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

25 Undue experimentation would be required to determine conditions substantially different from those of the operative examples that would provide results equivalent to those of the operative examples. Moreover, due to the unpredictability of chemical reactions, it would be unpredictable as to substantially different conditions that would provide

results disclosed in the specification. The claims must be commensurate in scope with the description of the embodiments of the invention in the specification that have been shown to produce the desired results.

The following is a quotation of the second paragraph of 35 U.S.C.

5 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by claims 1 and 17 being unclear as whether the acid in (b) of claim 1 and in (c) of claim 17 is
15 the same or is different from the organic acid being recovered. It does appear the acid in (b) and (c) can be the same as the organic acid recovered for the process to function as disclosed in the specification, and this should be clear in the claims.

The term "product (a)" in (b) of claims 1 and 17, "suspension (b)"
20 in (c) of claim 17 and "organic acid (d)" in line 2 of claim 31 are confusing since (a), (b) and (d) each represent a process step rather than a product, suspension or organic acid. It is suggested that -- from step -- be inserted after "product", "suspension" and "acid", and in line 2 of claims 1 and 17, after "comprising" insert -- the following steps --
25 .

Claim 2 and other claims that recite "step" are confusing by not having clear antecedent basis for "step" in claims 1 and 17. The above

insertion suggested after "comprising" in claims 1 and 17 will provide clear antecedent basis.

In line 1 of claims 5-13, 21, 22 and 24-28, the term "at step", and in line 1 of claim 23, the term "at steps" are confusing. It is
5 suggested that "at" be changed to -- in --.

Claims 5 and 21 are confusing by not having antecedent basis for "said organic acid added to said lower alcohol" since claims 1 and 17 do not require adding organic acid to the lower alcohol.

Claims 7 and 23, are confusing by not having clear antecedent basis
10 for "the reaction temperature". Claims 1 and 17 do not require a reaction temperature.

Claim 8 is confusing by not having antecedent basis for "addition of said acid". Claim 1 does not require addition of an acid.

Claim 9 is unclear by limiting an amount of acid added in step (b)
15 of claim 1 since step (b) of claim 1 does not require adding acid.

In line 2 of claim 16, -- from step -- should be inserted after "acid" to be clear since (c) represents a step rather than an acid.

In claims 6 and 22, "the process for drying" does not have clear antecedent basis. It is suggested that "the process for" be deleted.
20 For the same type of reason, "the process for" in claims 13 and 28 should be deleted.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumpelmann et al (5,852,211) in view of Bott et al (0 174 624) (both listed on form PTO-1449).

The claims are drawn to recovery of an organic acid from a fermentation broth by drying the broth to produce a dried product, adding the dried product to a lower alcohol in the presence of an acid and removing insolubles by to obtain the organic acid. The organic acid can be 2-keto-L-gulonic acid and the acid present when the dry product is added to the lower alcohol can be sulphuric acid.

Dumpelmann et al disclose a process for obtaining 2-keto-L-gulonic acid (KGA) from a fermentation solution containing the sodium salt of 2-keto-L-gulonic acid (NaKGA) that results from neutralization. The process involves crystallizing the sodium salt (NaKGA) and separating the resulting crystals from the fermentation solution, suspending the NaKGA crystals in a lower alcohol acidified to a pH of about 1.5 to about 3.5 with an acid such as sulphuric acid where the acid is converted to an insoluble sodium salt and the NaKGA is converted to free KGA, and

removing the insoluble sodium salt of the acid to obtain an alcoholic solution of the KGA. Afterwards, the free KGA may be esterified by alcohol of the alcoholic solution in the presence of a catalytic amount of acid to obtain an alkyl ester of the KGA. For example, see col 4,
5 lines 10-33, and Examples 1-3.

Bott et al disclose producing alkyl lactate esters by filtering a crude fermentation mixture containing calcium lactate, spray drying the resulting filtrate to obtain solid calcium lactate, reacting the solid calcium lactate with an alcohol in the presence of an acid that forms a
10 water-soluble calcium salt and isolating the lactic acid ester formed.

It would have been obvious to omit crystallizing NaKGA in the process of Dumpelmann et al and instead filter the fermentation solution, dry the resulting filtrate and react the dried filtrate with the lower alcohol in the presence of acid as suggested by Bott et al using steps of
15 filtering and drying a fermentation solution without crystallizing in the production of a lactic acid ester from a fermentation mixture containing a calcium salt of the lactic acid. Filtering and drying without crystallizing would have been expected to simplify the process of Dumpelmann et al, and such simplification would have been motivation to
20 use filtering and drying in place of crystallizing and separating the crystals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 303-0520. The examiner can normally be reached on
25 Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number
5 (703) 308-4743.

The fax phone number is (703) 305-3014 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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14.2/14
DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1285/

DMN
15 3/13/02